MASSACHUSETTS PESTICIDE BOARD SUBCOMMITTEE

OPERATIONAL PROCEDURES

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Approved by: Philmore Anderson III, State Purchasing Agent

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PREAMBLE

These operational procedures have been adopted by the Pesticide Board Subcommittee for the purpose of documenting and explaining the working procedures of the Pesticide Board Subcommittee regarding Pesticide registration issues subject to the appropriate sections of the Massachusetts pesticide Control Act (Chapter 132B of the M.G.L.) and accompanying regulations (Sections 3,7, and 8 of 333 CMR).

These operational procedures will be distributed to and available to advisory councils, appropriate state agencies, registrants, and Extension Service Personnel. It will also be provided to any interested individual upon written request.

SECTION I: General Business

A. Meeting Dates, Times, and Location

One meeting a month will be scheduled by the Pesticide Board Subcommittee. A second meeting may be scheduled, if necessary. The meeting will be scheduled for the third Wednesday of every month. Every attempt will be made to schedule at least two meetings a year in locations other than Boston.

Meetings will generally begin at 9:30 AM. Any meeting that runs to 12:30 PM will break for 45 minutes at the discretion of the Subcommittee.

B. Subcommittee Chairperson

The director of the Division of Food and Drugs of the Department of Public Health shall serve as Chairperson of the Subcommittee (see M.G.L. Chapter 132B, Section 3A).

C. Briefing Packages/Information Submitted to Subcommittee

A briefing package provided to the Subcommittee members prepared by the subcommittee staff must be provided at least ten (10) days before the meeting date. If said package is not received by all Subcommittee members ten days before the meeting, the chairperson, at the request of at least one other Subcommittee member, may decide to cancel certain or all of the agenda items scheduled for that meeting.

Registrants, advisory councils, and other interested parties are advised that in order to assure full consideration, written testimony should be submitted to the Subcommittee. All written testimony should be distributed to Subcommittee members at least five (5) days prior to the meeting date. If parties elect to use the DFA for distribution, five (5) copies of all written material are required fifteen days prior to the meeting date.

D. DFA Secretary to the Subcommittee

The Pesticide Program Director (hereinafter referred to as the Pesticide Bureau Chief) shall act as secretary to the Subcommittee. The Duties of the secretary are set forth in 333 CMR 3.05 (9) as follows:

1) Prepare and send required notices of meeting and proposals;
2) Preserve all records, reports and official documents of the...Subcommittee except those specifically assigned to the custody of others;
3) Shall be in charge of all correspondence having to do with the...Subcommittee;
4) Shall receive and account for all monies paid into the...Subcommittee and shall deposit it in the receipt accounts;
5) Take careful and authentic notes on all actions at meetings of the...Subcommittee. Prepare minutes from these notes and enter them in the official minutes book. Present the minutes to the...Subcommittee prior to the next meeting, recording any corrections and certifying them by his signature when the...subcommittee has approved them;
6) issue and sign on behalf of the ...Subcommittee such registrations and permits as the regulations require.

E. Motions

At the discretion of the chairperson, any motion made by any Subcommittee member shall be put in writing. If necessary, this may require a break in the meeting.

F. Priorities/Agenda Items

At the end of each meeting, staff and members of the subcommittee will consider a list of agenda items as recommended by the DFA, DPH, advisory councils, or any interested party for the next meeting. The subcommittee will review this list, set priorities, and establish an agenda for the next meeting. The final agenda for each meeting will be distributed no more than fourteen but no less than 7 days before each meeting to Pesticide Board members, Subcommittee members, advisory councils, and all individuals listed on the DFA mailing list.

On October 1 and April 1 of each year, the Subcommittee shall establish a list of registered pesticides for which individual review is necessary based on the criteria set forth in Section VI(B). The Subcommittee shall also set a tentative timetable for their review at these meetings.

G. Annual Lists and Updates

During October of each year, the DFA shall provide each Subcommittee member with the following lists, and will provide a monthly update as necessary:

1) All active ingredients classified by the federal EPA as Special Review;

2) The number of products currently registered in Massachusetts which contain any active ingredient on list (1) above. This list shall include a brief description of the registered uses of these products (for example, termiticide, herbicide, etc.);

3) All products currently registered in Massachusetts as a Special Local Needs registration (SLNs -- under section 24-c of FIFRA) and those products granted an Experimental Use Permit (EUP). This list shall include a brief description of the use of these products, the status of reports which are required for all products given an EUP, and any reports which were required as a condition for granting an SLN; and

4) All actions occurring in the previous year regarding appeals of any subcommittee decision.

SECTION II: Delegation of Routine Re-Registration to the Pesticide Bureau Chief

A. Purpose

The Subcommittee delegates authority to the Pesticide Bureau Chief to approve routine re-registrations.

B. Routine Re-Registration

The pesticide Bureau Chief is authorized to re-register any pesticide for a use or uses if at the time the application for re-registration is being reviewed by the pesticide Bureau Chief:

1) The pesticide product is registered for such use or uses with the federal EPA and was registered the previous year in Massachusetts pursuant to chapter 132B, Section 7 of the M.G.L.;

2) The re-registration for such use or uses is not prohibited by any federal or state law or regulation, Subcommittee decision, or pending subcommittee decision;

3) The label of the pesticide product has been approved by the federal EPA and complies with all federal and state labelling requirements including, but not limited to:

   (i) the inclusion of the manufacturer's EPA establishment number;
   (ii) the inclusion of the manufacturer's address; or
   (iii) the inclusion of the manufacturer's EPA registration number.

4) There has been no significant change in use or application site (i.e., no change from non-food use to food use outdoor use to indoor use); and

5) There has been no new information which raises concerns for unreasonable adverse effects on man or the environment.

C. Pesticide Product Identification

Products with identical EPA registration numbers and distributor number shall be recognized as one product for the purpose of registration except as below:

1) The product is marketed by separate distributors and is identified with a different trade name; or
2) The product contains significant differences in the use pattern identified on the product label as determined by the DFA and is marketed under a different trade name.

D. Mislabeled Products

If the label of a pesticide for which re-registration is sought contains any of the deficiencies list in Section B (3) above, the Pesticide Bureau Chief shall not register the product but shall write to the registrant stating:

1) The nature of the deficiency; and
2) That unless the registrant provides, within thirty days, a satisfactory explanation of the way in which the deficiency will be corrected, the product will not re-registered.

If the registrant provides the required explanation, and if the pesticide Bureau Chief finds that the registrant will expeditiously correct the deficiency, and that the existence of the deficiency pending correction will not pose a threat of unreasonable adverse effects on man or the environment, then the pesticide Bureau Chief is authorized to re-register the product. If the registrant does not satisfy the requirements necessary to re-register the product, the Bureau Chief will notify the Chairperson, who will schedule the application for consideration before the Subcommittee.

E. Timely Re-Registration of the Pesticides by Registrants

Section 8.04 of 333 CMR describes the application procedure for the registration of pesticides in Massachusetts. The registration year begins on July 1 and ends on June 30 of the following year. Each pesticide registration must be renewed annually by the registrant by July 1.

If an application to re-register a pesticide product registered the previous year is received by DFA on or before July 1, it will be processed within 90 days. During that time, the product continues to be registered. If an application to re-register a pesticide product registered the previous year is received by DFA after July 1, the product listed on the application is not registered in Massachusetts between July 1 and the actual date of approval by the Subcommittee. During this time period, if an official from the DFA documents the presence of said pesticide product on a retail or wholesale shelf or in the possession of an applicator, it will be considered a violation of Section 6 of chapter 132B of the M.G.L.

SECTION III: New Registration Applications

A. Definitions

A new pesticide registration application is any application for a pesticide product which was not registered in Massachusetts the previous registration year, or not routinely re-registered as described under Section II of this policy.

B. Procedures for New Registrations

New pesticide product registration applications will be sent to staff of the Departments of Food and Agriculture and Public Health to review. Staff will present a summary of their review to the Subcommittee. This summary will include but not be limited to the name of the product, its EPA registration number, the name of the registrant, and the active ingredient in the product. A vote for the approval to register these products will occur at a monthly Subcommittee meeting. New product registration applications not approved for registration will be subject to an individual review.

C. Criteria for Identifying New Registrations for Individual Review

The following criteria will be used by staff to identify new registration products which should undergo individual review by the Subcommittee:

1) The requirements stated in 333 CMR 8.05(4)(b) (see Appendix 8);
2) The presence of a new active ingredient;
3) Any significant change in application site (e.g. from outdoor to indoor, from non-food to food);
4) If the magnitude of use and exposure potential warrants Subcommittee review;
5) Any EUP application;
6) Mislabelled products;

D. Any subcommittee Member May Request an Individual Review of a New Registration Application

E. Notification to Registrants Regarding the Determination of the Subcommittee to Conduct an Individual Review of a New Registration Application

Once the Subcommittee has determined to conduct an individual review of a new pesticide registration application, the registrant will immediately receive a certified letter stating that the application will not be processed until the Subcommittee completes an individual review and makes a final determination. The Subcommittee may at this time request additional information from the registrant for the individual review based on Section III(C) above. The Subcommittee will inform the registrant of the data requirements and of Subcommittee meetings which will be scheduled to review the application.

SECTION IV: Special Local Needs Registrations (SLNs)

A. Granting of an SLN

When a special local problem exists that can only be mitigated through the use of a particular chemical that is not federally registered for that particular use, that chemical's use is regulated through the issuance of a Special Local Needs registration. This authority is granted to a state under Section 24-C of FIFRA.

A true special local need can only be evaluated after the Subcommittee considers the health effects, costs, safety, efficacy, and environmental benefits and risks relative to existing federal or state registrations. If there exists a federal or state pesticide registration which better fulfills the stated need, taking into account the above mentioned costs and benefits, a special local need does not exist.

B. Minimum Application Requirements

All SLN applications must be initiated in writing by a qualified individual or group representing the end-user, such as the Cooperative Extension Service. For the purposes of this policy, "qualified" means someone with an academic background and/or field experience in a subject area directly associated with the special local need.

1) From the initiator (see Appendix 2):

   (i) Name of the product and percent active ingredient;
   (ii) Name and description of the site and pest;
   (iii) Use: If applicable, number of acres to be applied, percent active ingredient per area of application, method of application, application rates, and applicator protection;
   (iv) To the best of his knowledge, documentation as to what has been used in the past on that site for that pest;
   (v) Full documentation (such as studies) of the existence of a true special local need, (e.g., efficacy of alternatives, possible economic loss, etc.)

2) From the registrant (See Appendix 3):

   (i) Toxicology information;
   (ii) Environmental fate information;
   (iii) Efficacy data;
   (iv) Statement as to whether or not environmental fate or efficacy data were generated in Massachusetts or New England, and, if so, copies of studies;

(v) The status of the same SLN application in other states;
(vi) Statement as to whether or not a federal registration (section 3 of FIFRA) is being pursued;
(vii) A $100 fee payable to the Commonwealth only if the SLN is granted.

The Subcommittee will not consider an SLN application until all the information requested above is received.

C. Presentation of Information to the Subcommittee

1) Background, including but not limited to, actions in other states,history of product review by Subcommittee, and action by the EPA;
2) Toxicology (Appendix 4), including a summary of the pros and cons of granting the SLN based on the toxicology data;
3) Environmental fate (Appendix 4), including a summary of the pros and cons of granting the SLN based on the environmental fate data;
4) Benefits information (Appendix 5), including a summary of the pros and cons of granting the SLN based on the benefits information;
5) Alternatives/existing registrations, including toxicology, environmental fate, and benefits information on each alternative (Appendices 4 and 5);
6) List of alternative risk/management actions that could be taken by the Subcommittee.

D. Expiration Date

The Subcommittee will review each SLN five (5) years after its approval date. However, a 1-year evaluation will be set if the Subcommittee determines that registration will only be for a one-year period conditional upon the receipt of new information (e.g. residues, toxicology data, environmental fate data, etc).

Between January 1, 1987 and January 1, 1989, the Subcommittee will review all SLNs in existence on January 1, 1987.

SECTION V: Experimental Use Permits (EUPs)

A. Definition

An EUP is defined in 333 CMR 7.03 (see Appendix 6).

B. Minimum Application Requirements

The registrant shall complete the form provided by the Bureau (see Appendix 7) and submit a $100.00 application fee. The information includes:

1) Name, type, and EPA registration number of the product;
2) Federal EUP number and effective date of EPA permit;
3) Quantity authorized by EPA;
4) Purpose or objectives of proposed testing;
5) Target pest, amount of pesticide proposed for use, method and description of application, proposed testing dates, and location of application;
6) Plan for disposal of unused pesticide and treated material;
7) Supervision, program participants and letters from cooperators indicating their participation;
8) Toxicology information; and
9) Environmental fate information.

The Subcommittee will not consider an EUP application until the information requested on the form is provided.

C. Presentation of Information to the Subcommittee by Staff

Presentation of information will be presented for the following, as described in Section IV(C) above.

1) Background;
2) Toxicology information (see Appendix 4);
3) Environmental fate information (see Appendix 4); and
4) List of alternative risk/management actions that could be taken by the Subcommittee.

D. Registrant Obligation for Submission of Report of Results

All registrants are required under Section 7 of 333 CMR to submit to the DFA a report of the results of an EUP granted in Massachusetts six (6) months after the completion of the experiment.

Section VI: Individual Review of Active Ingredients

A. Definition

An individual review is any review for re-consideration of an existing registration (change of use classification, suspension, revocation or other limitation) or any review for a new registration application which raises concern for unreasonable effects on man or the environment.

B. Placement of an Active Ingredient on Individual Review May Include, But Not Be Limited to, the Criteria Spelled Out in 333 CMR 8.05(b)(see Appendix 8)

For the purposes of this policy, the following criteria are spelled out below to highlight some especially important considerations:

1) The potential for causing unreasonable adverse effects to the environment based on:
   (i) animal toxicity information;
   (ii) human health effects information;
   (iii) potential for exposure based at least in part on use data in Massachusetts or other states including an assessment of the routes of exposure; or

2) The potential for causing unreasonable adverse effects to the environment based on:

   (i) soil and water persistence date;
   (ii) existence of groundwater monitoring data and other environmental exposure information
   (iii) impact on bees, aquatic organisms, wildlife and other non-target organisms and areas; or

3) The active ingredient is targeted for EPA's Special Review.

C. Presentation of Information to the Subcommittee

1) Background, including, but not limited to, actions in other states, history of product review by Subcommittee, and action by the EPA;

2) Toxicology (see Appendix 4), including a summary of the pros and cons of granting the registration based on the toxicology data;
3) Environmental Fate (see Appendix 4), including a summary of the pros and cons of granting the registration based on the environmental fate data;
4) Benefits information (see Appendix 5), including a summary of the pros and cons of granting the registration based on the benefits information;
5) Alternatives of the product, including their toxicology, environmental fate, and benefits information (appendices 4 and 5);
6) A list of risk/management of actions that could be taken by the Subcommittee (i.e., modification, suspension, revocation, state limited use, additional conditions of use, etc.).

Recommendations to the Subcommittee by the staff as to which action should be taken will not be made until the subcommittee meeting.

D. Requests/Recommendations to the Subcommittee to Consider Conducting an Individual Review

Any individual, group, or Massachusetts state agency may request that the Subcommittee consider conducting an individual review on any active ingredient currently registered for use as a pesticide in Massachusetts or on any new registration application before the Subcommittee. Such a request shall be submitted to the Subcommittee Chairperson. The request may be considered at the following monthly meeting when the Subcommittee considers upcoming priorities and agenda as detailed in Section I (F) of this policy. the registrant will be notified at least seven days before the meeting that the Subcommittee will be considering whether to conduct an individual review.

E. Notification to Registrant Regarding the Intent of the Subcommittee to Conduct an Individual Review

Once the Subcommittee has voted to conduct an Individual Review, all registrants will receive, when possible, at least thirty (30) days notice that one or more of their pesticide product registrations is to be reviewed as stated in Section VI (A) above.

F. Criteria Used for Modifying the Use Classification for Existing Registrations

The determination of whether or not sufficient evidence exists to change the use classification of a currently registered pesticide product may include, but not be limited to, the criteria listed in 333 CMR 8.05(4)(c) items 1-14 (See Appendix 9).

SECTION VII. Procedure for Registrant to Voluntarily Cancel Product Registrations

A. Definition

Voluntary cancellation of a pesticide product means that the registration has been withdrawn by the registrant. Registering a product for "discontinued use" is not considered voluntary cancellation.

B. Procedure

The Pesticide Bureau Chief will accept requests from registrants or their representatives to voluntarily cancel any pesticide product registrations. This should be done through a notice which should be sent by certified mail to both the chairperson of the Subcommittee and the Pesticide Bureau Chief. The notice shall include the following information:

1) The pesticide products of concern, listed by product name and EPA Registration Number;
2) The Reasons for the voluntary cancellation;
3) An estimate of the quantity of the products within the Commonwealth; and
4) A description of a plan to dispose, transport, or otherwise take care of the material within a stated period of time.

C. Subcommittee Action

The Subcommittee will determine the final date by which any remaining products must be withdrawn.

SECTION VIII: Release of Subcommittee Business Documents to Pesticide Board Advisory Council and the General Public

With the exception of confidential information, all subcommittee records and information are part of the public record and are public documents.

A. Minutes of Subcommittee Meetings:

Advisory Council Chairmen will be given copies of meeting minutes after they have been approved by the Subcommittee.

B. Subcommittee Information Packages

The DFA will make every effort to keep the Advisory Councils apprised of issues under consideration by the Subcommittee. Where appropriate, a final package may be provided to specific council chairmen for input prior to a decision.

C. Subcommittee Decisions

Summaries of all subcommittee decisions will be provided to both Advisory Councils and the general public upon written request.

APPENDICES

APPENDIX 1

Criteria for Reviewing
New product Applications

Taken from 333 CMR 8.05

(c) Criteria for registration and Classification. The Subcommittee shall register and classify a pesticide or pesticide use if it determines that its composition is such as to warrant the proposed claims for it; its labeling and other material required to be submitted comply with the requirements of 333 CMR 8.00: it will perform its intended function without unreasonable adverse accordance with widespread and commonly practice it will not generally cause unreasonable adverse effects on the environment. In reaching its decision on registration and classification the Subcommittee may consider a number of factors, including but not limited to, the following:

1. The economic, social and environmental costs and benefits of the pesticide or pesticide use.
2. Material submitted pursuant to 333 CMR 8.04(2).
3. The recommendation of the Board.
4. Evidence relevant to the factors set forth in 333 CMR 8.05(4)(b).
5. Effects of toxicological significance including but not limited to, neurological or behavioral alterations and liver changes.
6. Mutagenesis
7. Teratogenesis
8. Carcinogenesis
9. Severe skin or eye irritation
10. Persistence of the pesticide or break-down product.
11. Bioaccumulation of the pesticide or break-down product.
12. Risk of contamination non-target organisms and thereby causing acute, chronic; delayed or secondary adverse effects.
13. The extent to which ingredients or break-down products have the potential to move from the target area.
14. Synergistic effects

(d) All registrations shall be issued subject to all requirements imposed by the Massachusetts Pesticide Control Act, FIFRA, and the regulations promulgated under either.

(5) Notification of Decision. The subcommittee Shall notify the applicant promptly, after making a decision. If the Subcommittee denies a registration or classified a pesticide or pesticide use different than the Environmental Protection Agency classification, notification shall be given to the Board and by certified letter to the applicant and shall set forth the reasons and factual basis for the determination, and the conditions, if any, which must be ratified in order for the registration to be approved or the classification altered. The applicant will have thirty days from the date of receipt to take the specified corrective action.

(6) Applications to Amend or Supplement a Registration. Applications to amend or supplement a registration shall be submitted by the registrant whenever he is required to submit an application to amend or supplement a registration to the Environmental Protection Agency pursuant to the regulations under FIFRA, as amended. Applications to amend or supplement a registration shall be submitted in the manner set forth in 333 CMR 8.04, and shall be disposed of in the manner set forth in 333 CMR 8.05.

APPENDIX 2

Special Local Needs (SLN or 24-C)
Initiator Form

MASSACHUSETTS SPECIAL LOCAL NEEDS INITIATION FORM

Name & Address of Initiator	Title of Applicant
	Telephone
	Date of Application / /

PART 1: Product Information

1. Name of Product
2. Active Ingredient (list percentage in product)
3. Manufacturer/Registrant
4. Registrant Contact

PART 2: Site/Pest Information

1. Pest(s) of Concern	2. Sites(s) of Concern
3. Approximate acreage and location in Massachusetts Acreage: Approximate location of acreage:	

PART 3: Past Pesticide Use Information Against the Pest on the Site of Concern

List the pesticides which have been or are presently being used against the pest on the site of concern

Pesticide	Approx. Application Rate (lbs. active/A)	Comments on Efficacy

PART 4: Summary

Describe the existence of a true special local need. Please include any information or studies conducted on efficacy of current products and real or potential economic loss if the 24-c is not approved

PART 5: Preferred Dates of Treatment

Last preferred date for start of application:

Signature of Initiator

APPENDIX 3

Special Local Needs (SLN or 24-C)
Registrant Form

MASSACHUSETTS SPECIAL LOCAL NEEDS APPLICATION FORM

Please fill out the form completely and submit five (5)copies (along with five copies of any attachments) to the attention of: Registration Specialist, Department of Food and Agriculture, Pesticide Bureau, 10 Cambridge Street, Boston, MA 02202.

PART 1: Product Information

Name and Address of Registrant	Date of Application / /
	Contact
	Telephone
Product Name	EPA Reg. No
Active Ingredient(s) with percentages	Proposed Use(s)
Proposed Application Rate	Range of Application Rates on Currently Registered EPA Label

PART 2: Efficacy

1. Summary of Efficacy Data (please attach reports)
2. Has any Efficacy Data been generated in New England? If "yes", please list state(s):

PART 3: Environmental Fate

1. Summary of Environmental Fate (please attach reports)
2. Has any Environmental Fate been generated in New England? If "yes", please list state(s):

PART 4: Toxicology Information

1. Acute Toxicity Information (summarize and attach reports); include rat oral LD50 and rabbit dermal LD50 if available.

2. Chronic Toxicity Information (summarize and attach reports):

   a. Oncogenic studies

   b. Mutagenic studies

   c. Reproductive studies

   d. Neurotoxic studies

   e. Other chronic studies

3. Other (e.g., non-target organisms studies, etc):

4. Any existing health based guidelines (EPA, ADIs, FDA, WHO, etc.)

5. Exposure information, such as levels that have been found in drinking water, foods, air, or in applicator studies.

6. Attach an updated bibliography concerning the toxicity of the pesticide, including any review articles such as those by the FAO/WHO, EPA, FDA, and others.

PART 5: Residues in Food or Feed (if applicable)

1. Tolerance and Federal Register citation on commodity named in the application:

2. Residues found from actual use data: (Please list below only those data relevant to the commodity in the application at the proposed application rate. Any other data may be submitted as an attachment:

Application Date	Date Sample Taken	Residue Found (Conc.)

PART 6: Registration Status

1. Have you applied for this 24-c in any other State:

2. If "yes", please list the states and application status, (approved, pending or denied).

State	Registration Status

3. Have you applied for a Section 3 (federal) registration for this product for use on the stated site:

If "yes", date of submission to EPA _____

If "no", please briefly explain why:

_____

Signature of Authorized
Representative of the Registrant

APPENDIX 4

Format for Presentation of Toxicology and Environmental Fate Data to the Subcommittee by Staff

Toxicology and Environmental Fate Data

The subcommittee will receive a summary of Toxicology and Environmental Fate data from staff which may include the following information:

1. Identification of active ingredient

2. Identification of producers

3. Chemical and physical properties

4. Pesticide uses

5. Massachusetts registration information

    a. number of products
    b. range in percent active ingredient

6. Environmental Fate

    a. average half-life in soil, water, and air
    b. hydrolysis, photolysis rates
    c. persistence, bioaccumulation, and translocation

7. Toxicology

8. Regulatory information

    a. guidelines (federal/state/international, for drinking water air, etc.)
    b. actions taken regarding pesticide in other states/federal other countries/manufacturers/users.

APPENDIX 5

Format for Presentation of Benefits Information to the Subcommittee by Staff

Chemical _____

Classification _____

PESTICIDES BENEFITS

DATE SHEETS

Primary Cost

1. Retail Cost of chemical by unit
2. Cost of chemical in lbs. active/A

Use(s)

1. Primary Uses
2. Percentage of use in each use named above:

Use	Percentage of Use vs. Pest of Named Chemical Vs. Alternatives

1. In Massachusetts

Use	Quantity

2. Other (i.e. regional, national or other state estimates)

Use	Quantity

Estimated Losses if Registration Discontinued

Use	Quantity

APPENDIX 6

Definition of an Experimental Use permit (EUP)

TAKEN FROM SECTION 7 OF 333 CMR.

7.03: Permit Requirement

(1) State experimental use permits are required to control potential hazards of pesticide experimentation under out-of-door, greenhouse, and domestic animal trial conditions. State Experimental use permits are not required for indoor experimentation excepting greenhouse and animal test work as specified in 333 CMR 7.00.

(2) All pesticide applications made pursuant to a state experimental use permit must be applied by an applicator certified in category 10 Demonstration and Research or by someone acting under the direct supervision of such a certified applicator.

(3) A state experimental use permit will be required for all experimentation, except as provided for under 333 CMR 7.03(4)(b), with any "new chemical" for which a Federal experimental use permit requirements under 40 CFR 172.3. A state experimental use permit will not be issued for any other use of a new chemical.

(4) State experimental use permits will further be required as follows:
(a) Outdoor applications
1. Experimental use of "new chemicals" shall be accordance with 333 CMR 7.03(3).
2. Experimentation involving "unregistered uses" and "new Products"
a. Where plot size is less than 1/4 acre - A state experimental use permit will not be required where an "unregistered use" or a "new product" is applied to less than 1/4 acre.
b. Where plot size is between 1/4 and 10 acres - A state experimental use permit is required only if the application rate of any active ingredient is higher than any application rate registered by EPA for any other use of the compound regardless of crop.
c. Where plot size is over 10 acres - A state experimental use permit is required for all experiments that involve the application of an "unregistered use " or a "new product" to more than 10 acres.
d. Where the material is applied by aircraft - A state experimental use permit is required for all experiments that involve the application of an "unregistered use" or a "new product" by aircraft.

(b) Greenhouse Applications. A state experimental use permit will be required in two cases:
1. Experiments involving a "new chemical" applied to more than 100 sq. ft. of greenhouse bench space of plant material;
and
2. Experiments involving an "unregistered use" or a "new product" applied at a rate greater than any EPA registered rate for the active inert ingredients and applied to more than 100 sq. ft. of greenhouse bench space of plant material.

(c) Application to animals. With regards to domestic animals experimentation, such

as tests on cattle, sheep, poultry or other species of farm or domestic animals, a state experimental use permit is required when more than 10 individuals of a large species (cow,hog, sheep, horse, etc.) or 25 individuals of a small species (cat,dog, etc.) or 50 individuals of poultry are to be treated with either a "new product" or an unregistered use compound for which the rate is greater than any rate registered by EPA for that active ingredient's use on any other species of animal. State experimental use permits are not required for laboratory testing of pesticide on rodents or other species when conducted at a research facility on animals purchased and maintained exclusively for such experimentation and not part of an agricultural operation.

(5) Uses of food, feed, or animal products treated with pesticides covered by state experimental use permits:

(a) Plants - all raw agriculture food or feed crop treated with pesticides that exceed or do not have EPA established tolerance for the crops in question must be destroyed at the end of the experiment by burning or plowing under. Portions of food or feed crops utilized further in experimental animal feeding studies are excepted.

(b) Animals - All domestic animals treated with pesticides that exceed or do not have EPA established tolerances for the species and part (milk, meat, etc.) in question and which may be used for food or feed must be destroyed at the end of the experiment. Specific arrangements shall be made in the state experimental use permit to monitor declining residue levels when the temporary or established residue tolerance is expected to be exceeded.

(6) Permittee obligations - it is the responsibility of the permittee to assure that:

(a) All required state and/or federal experimental use permits are obtained.

(b) That applicators using experimental use permits be certified in Category 10 or are acting under the direct supervision of a certified applicator.

(c) That public access to experimental areas is appropriately limited by posting and/or fencing.

(d) That food or feed items unfit for consumption due to illegal pesticide residues are destroyed.

APPENDIX 7

Experimental Use Permit Application

Application For An Experimental Use permit

In accordance with regulations promulgated pursuant the Massachusetts Pesticide control Act (333 CMR7.05) this application for an Experimental Use Permit must be completed in full and filed/with the Pesticide Board Subcommittee along with experimental label, a copy of the EPA Experimental Use Permit and the permit fee of one hundred dollars ($100.00) and such other information as the Subcommittee may require. The fee is payable by check or money order to the Commonwealth of Massachusetts and shall be waived for applications by government agencies.

PLEASE SUBMIT FIVE COPIES

Date of Application _____/_____/_____

Part I: Product Identification

<table>
<tr><td rowspan="3">1. Name and Address of Applicant</td><td>Signature of Applicant or Authorized Representative</td></tr>
<tr><td>Title</td></tr>
<tr><td>Telephone</td></tr>
<tr><td>2. Product Name</td><td>3. Product Type</td></tr>
<tr><td colspan="2">4. Registration Number of Product if Registered with EPA</td></tr>
<tr><td colspan="2">5. Federal Experimental Permit Number if Issued by EPA</td></tr>
<tr><td colspan="2">6. Effective Date of EPA Permit _____/_____/_____ to _____/_____/_____</td></tr>
<tr><td colspan="2">7. Quantity Authorized by EPA</td></tr>
</table>

Part II: Purpose or Objectives of Proposed Testing

Part III: Proposed Experimental Program

1. Designation of pest organism(s)
2. Amount of pesticide proposed for use
3. Method of application
4. Proposed dates or periods during which the testing program is to be conducted
5. Location of application(s)
6. Manner in which supervision of the program will be accomplished
7. Description of application (include information such as crops, sites,dosage rates and situation of application on or in which the pesticide is to be used)

8. Proposed method of storage and disposition of any unused experimental use pesticide and its containers

9. Disposal of treated crop - Proposed method of disposal of a treated commercial crop that does not meet environmental agency tolerance for that corp or for which no tolerance has been set

Part IV: Program participant(s) and Cooperator(s)

List all participant(s) in the program, whether or not in the employ of the applicant. Include name, street address, telephone number and qualifications of participant(s). The qualifications of the participant(s) must include participant(s) current Massachusetts Category 49 (Research and Demonstration) certification number.

Part V: Submission of Available Toxicological Data

Please submit with this application any toxicological data available. These may include but not be limited to: Acute Toxicity Information (summarize and attach reports); include rat oral LD50 and rabbit dermal LD50 if available; Chronic Toxicity Information (summarize and attach reports): Oncogenic studies, Mutagenic studies, Reproductive studies, Neurotoxic studies, Other chronic studies; Any existing health based guidelines (EPA, ADIs, FDA, WHO, etc.), Exposure information, such as levels that have been found in drinking water, foods, air, or in applicator studies; Attach an updated bibliography concerning the toxicity of the pesticide, including any review articles such as those by the FAO/WHO, EPA, FDA, and others.

List each item below.

APPENDIX 8

Criteria for Individual Review and Changes in use Classification for Existing Registrations

333 CMR 8:05(4)(b)

(b) Criteria for Individual Review. The Subcommittee shall individually review for registration and classification those pesticides and pesticide uses recommended by the Board and may individually review for registration and classification those pesticides and pesticide uses, including but not limited to those:

1. Being reviewed by the United States Environmental Protection Agency through its RPAR procedure or any other mechanism used to review federal pesticide registrations.
2. For which a special local needs application is submitted and for which there has been a hazards review consistent with the state plan approved by the Environmental Protection Agency pursuant to 40 CFR 162.
3. For which there is verifiable evidence that attributes of packaging, formulation, or common practice which runs contrary to the intent of label instructions and prohibitions, lead to a higher than normal probability of accidents, human illnesses or fatalities, or unreasonable adverse effects on the environment.
4. Intended or labeled for professional use.
5. Intended or labeled for aquatic use, excluding those intended for use in swimming pools.
6. For which tests indicate a buildup of residues of ingredients or breakdown products in mammalian foods, in amounts greater than or equal to acute mammalian LD50; or in avian foods, in amounts greater than or equal to subacute avian LC50.
7. Which used indoors, except in greenhouses, meets one or more of the following criteria:

Oral LD50	less than or equal to	500 mg/kg (product as sold except "Ready-to-Use")
	less than or equal to	2000 mg/kg (use dilution or "Ready-to-Use")
	or	
Dermal LD50	less than or equal to	2000 mg/kg (product as sold except "Ready-to-Use")
	less than or equal to	5000 mg/kg (use dilution or "Ready-to-Use")
	or	
Inhalation LC50	less than or equal	to 1 mg/1LC50 (product as sold except "Ready-to-Use")
	less than or equal to	4 mg/1 LC50 (use dilution or "Ready-to-Use")

8. Which used outdoors or in greenhouses meets one or more of the following criteria:

Oral LD50	less than or equal to	50 mg/kg (product as sold except "Ready-to-Use")
	less than or equal to	200 mg/kg (use dilution or "Ready-to-Use")
	or	
Dermal LD50	less than or equal to	500 mg/kg (product as sold except "Ready-to-Use")
	less than or equal to	1000 mg/kg (use dilution or "Ready-to-Use")

APPENDIX 9

Criteria for Registration and Classification

333 CMR 8:05(4)(c)

(c) Criteria for Registration and Classification. The Subcommittee shall register and classify a pesticide or pesticide use if it determines that its composition is such as to warrant the proposed claims for it; its labeling and other material required to be submitted comply with the requirements of 333 CMR 8.00; it will perform its intended function without unreasonable adverse effects on the environment; and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

In reaching its decision on registration and classification the Subcommittee may consider a number of factors, including but not limited to, the following:

1. The economic, social and environmental costs and benefits of the pesticide or pesticide use.
2. Material submitted pursuant to 333 CMR 8.04(2).
3. The recommendation of the Board.
4. Evidence relevant to the factors set forth in 333 CMR 8.05(4)(b).
5. Effects of toxicological significance including but not limited to, neurological or behavioral alterations and liver changes.
6. Mutagenesis
7. Teratogenesis
8. Carcinogenesis
9. Severe skin or eye irritation
10. Persistence of the pesticide or break-down product.
11. Bioaccumulation of the pesticide or break-down product.
12. Risk of contaminating non-target organisms and thereby causing acute, chronic, delayed or secondary adverse effects.
13. The extent to which ingredients or break-down products have the potential to move from the target area.
14. Synergistic effects

(d) All registrations shall be issued subject to all requirements imposed by the Massachusetts Pesticide Control Act, FIFRA, and the regulations promulgated under either.

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